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PATENT APPLICATION
Docket No.: DUK96-03pA

#6
J. S. Stamler
6/4/97

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jonathan S. Stamler

Serial No.: 08/616,371

Group: 1811

Filed: March 15, 1996

Examiner: B. Celsa

For: METHODS FOR PRODUCING AND USING
S-NITROSOHEMOGLOBINS

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
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GROUP 1811

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant respectfully requests a one-month extension of time to respond to the Office Action mailed from the U.S. Patent Office on March 19, 1997, setting forth a restriction requirement in the above-referenced application. A separate Petition for Extension of Time (one month) with authorization to charge the Petition Fee to Attorney's Deposit Account No. 08-0380, is being filed concurrently with this Response. Also being filed concurrently are a Preliminary Amendment and an Information

Disclosure Statement.

Applicant elects to prosecute, with traverse, the claims of Group IV (Claims 9-21 and 23-27), drawn to SNO-hemoglobins, methods for making SNO-hemoglobins, methods for delivering NO and O₂, methods for scavenging free radicals, and methods for treating medical conditions and diseases. Applicant reserves the right to file subsequent applications or take such other appropriate action as deemed necessary to protect the inventions of Groups I-III.

GROUND FOR TRAVERSAL

Classification of Claims 4 and 22

Claims 4 and 22, drawn to a method for preserving a living organ, have been designated Group II. On page 2, paragraph number 2 of the Restriction Requirement, the Examiner states that the inventions of Groups II and IV are related as product and process of use. According to MPEP § 806.05(h), the inventions are distinct if at least one of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. The Examiner offers as explanation for separate classification, "The methods of claims 23-27 address the treatment of different diseases involving different hosts and method steps and represent patentably distinct methods as compared to the use of S-nitrosated hemoglobin to preserve organs, which represents a non-therapeutic method."

Respectfully, it is not understood how Claims 23-27 "address the treatment of different diseases involving different hosts and method steps," as SNO-hemoglobin is used in all of these cases in the delivery of O₂ and NO to tissues. The method steps for preserving a living organ differ from those of the methods of the claims in Group IV only in that the SNO-Hb(FeII)O₂ is

administered to the organ outside the body in Claims 4 and 22. The methods of the claims do not involve different hosts, as the organ of Claims 4 and 22 can be from any animal, including human.

Classification of Claim 5

Claim 5, drawn to a method for treating malaria in a patient, has been included in Group III. On page 3, paragraph number 3 of the Restriction Requirement, the Examiner states that inventions I and III are unrelated. The Examiner states that "...the different inventions have different modes of operation, different function and different [effects] and additionally utilize different compounds in different methods which achieve totally different objectives." Applicant respectfully disagrees with this conclusion. The method of Claim 5 is merely the method of the claims of Group I performed on red blood cells *ex vivo* rather than *in vivo*. The mechanism by which the method accomplishes the desired effects is the same. The method of Claim 5 is administering a source of NO that will cause the modification of hemoglobin to nitrosated forms that will then be vehicles of delivery of NO and O₂. The method of Claim 5 and of the claims of Group I do not utilize different compounds. The method of Claim 5 uses S-nitrosothiol, which is a low molecular weight nitrosating agent. The objectives of Claim 5 and of the claims of Group I are the same--in broad terms, to deliver NO to the cells in a mammal. Further, a single search for the use of the nitrosating agents of the Group I claims in enhancing the delivery of O₂ and NO in a method of therapy would encompass prior art relevant to the claims of the present Groups I and III. Please note MPEP 904.01(d), which gives instruction on complete searches, and states *inter alia*

In outlining a field of search, the examiner should note every class and subclass under the U.S. Patent Classification System and other organized systems of literature that may have material pertinent to the subject matter as claimed. ... The search should extend to all probable areas relevant to the claimed subject matter and should discover the disclosed features which

might reasonably be expected to be claimed.
Thus, no burden is placed upon the Patent Office in the inclusion of both sets of claims in a single application.

Proposal for New Groups

Applicant requests consideration of the proposal that the claim of Group III (Claim 5) be combined with the claims of Group I, and that the claims of Group II (Claims 4 and 22) be combined with the claims of Group IV.

CONCLUSION

It is believed that the above re-grouping of the claimed subject matter will balance the rights of Applicant to obtain the full patent protection to which he is entitled and the cost considerations of the PTO. If the Examiner feels that a telephone conference would be helpful in expediting the prosecution of the application, the Examiner is encouraged to telephone the undersigned at (617) 861-6240.

Respectfully submitted,

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Dated: *May 13, 1997*